

## § 866.5785

measure by immunochemical techniques the rheumatoid factor (antibodies to immunoglobulins) in serum, other body fluids, and tissues. Measurement of rheumatoid factor may aid in the diagnosis of rheumatoid arthritis.

(b) *Classification*. Class II (performance standards).

### § 866.5785 **Anti-Saccharomyces cerevisiae (*S. cerevisiae*) antibody (ASCA) test systems.**

(a) *Identification*. The Anti-Saccharomyces cerevisiae (*S. cerevisiae*) antibody (ASCA) test system is an in vitro diagnostic device that consists of the reagents used to measure, by immunochemical techniques, antibodies to *S. cerevisiae* (baker's or brewer's yeast) in human serum or plasma. Detection of *S. cerevisiae* antibodies may aid in the diagnosis of Crohn's disease.

(b) *Classification*. Class II (special controls). The special control is FDA's "Guidance for Industry and FDA Reviewers: Class II Special Control Guidance Document for Anti-Saccharomyces cerevisiae (*S. cerevisiae*) Antibody (ASCA) Premarket Notifications."

[65 FR 70307, Nov. 22, 2000]

### § 866.5800 **Seminal fluid (sperm) immunological test system.**

(a) *Identification*. A seminal fluid (sperm) immunological test system is a device that consists of the reagents used for legal purposes to identify and differentiate animal and human semen. The test results may be used as court evidence in alleged instances of rape and other sex-related crimes.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 866.9.

[54 FR 25047, June 12, 1989, as amended at 66 FR 38793, July 25, 2001]

### § 866.5820 **Systemic lupus erythematosus immunological test system.**

(a) *Identification*. A systemic lupus erythematosus (SLE) immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the autoimmune antibodies in serum and other body fluids that react with cellular nu-

## 21 CFR Ch. I (4-1-13 Edition)

clear double-stranded deoxyribonucleic acid (DNA) or other nuclear constituents that are specifically diagnostic of SLE. Measurement of nuclear double-stranded DNA antibodies aids in the diagnosis of SLE (a multisystem autoimmune disease in which tissues are attacked by the person's own antibodies).

(b) *Classification*. Class II (performance standards).

### § 866.5860 **Total spinal fluid immunological test system.**

(a) *Identification*. A total spinal fluid immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the total protein in cerebrospinal fluid. Measurement of spinal fluid proteins may aid in the diagnosis of multiple sclerosis and other diseases of the nervous system.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 866.9.

[47 FR 50823, Nov. 9, 1982, as amended at 61 FR 1119, Jan. 16, 1996; 66 FR 38793, July 25, 2001]

### § 866.5870 **Thyroid autoantibody immunological test system.**

(a) *Identification*. A thyroid autoantibody immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the thyroid autoantibodies (antibodies produced against the body's own tissues). Measurement of thyroid autoantibodies may aid in the diagnosis of certain thyroid disorders, such as Hashimoto's disease (chronic lymphocytic thyroiditis), nontoxic goiter (enlargement of thyroid gland), Grave's disease (enlargement of the thyroid gland with protrusion of the eyeballs), and cancer of the thyroid.

(b) *Classification*. Class II (performance standards).

### § 866.5880 **Transferrin immunological test system.**

(a) *Identification*. A transferrin immunological test system is a device that consists of the reagents used to